

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

EARL RINGO, et al.,)
)
Plaintiffs,)
)
vs.) **No. 09-4095-CV-C-NKL**
)
GEORGE A. LOMBARDI, et al.,)
)
Defendants.)

**Reply to Defendants' "Reply to Plaintiff's Supplemental Suggestions"
Concerning Cross-Motions for Summary Judgment**

For the first time in these proceedings, Defendants advance a novel argument that their protocol actually conforms with federal law, so that compliance with both is not “impossible” for purposes of preemption. *See* “Reply to Plaintiff’s Supplemental Suggestions,” (ECF Doc. 259), at 3-4. Defendants cite a regulation under the Controlled Substances Act, which permits an individual practitioner to “administer or dispense directly a controlled substance without a prescription.” ECF Doc. 259, at 3, citing 21 C.F.R. § 1306.11(b). Defendants argue that the definition of “administering” a drug under the CSA includes “the direct application of a controlled substance by a practitioner, or in his presence by his authorized agent.” *Id.*, citing 21 U.S.C. § 802(2)(a). Therefore, the argument goes, DEA-registered physician M3 may, without issuing a prescription, freely administer the controlled substance sodium thiopental by watching his non-

medical supervisee inject the drug. ECF Doc. 259, at 3-4. Defendants essentially liken their protocol to what happens in hospitals or doctors' offices, when a nurse might give narcotic pills to a patient under a physician's direction and supervision.

Defendants are wrong. They neglect to mention essential qualifying language within the regulation they cite:

An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II ***in the course of his professional practice*** without a prescription

21 C.F.R. § 1306.11(b) (emphasis added).¹ The defense-omitted language is not mere surplusage. It is essential to the statutory and regulatory scheme of the CSA, which makes it unlawful for medical practitioners to dispense and administer controlled substances "when their activities fall outside the usual course of professional practice." *United States v. Moore*, 423 U.S. 122, 124 (1975); *United States v. Kanner*, 603 F.3d 530, 533 (8th Cir. 2010). The regulation parallels statutory language underlying these precedents. See 21 U.S.C.A. § 802(21) ("practitioner" is a professional licensed to dispense, administer, or distribute controlled substances "in the course of professional practice or research"); *Moore*, 423 U.S. at 141-42.

The point is that a licensed practitioner may not rely on just any "agent" to medicate a patient with controlled substances. Rather, the drug must be dispensed

¹Plaintiffs will simply assume, *arguendo*, that the regulation applies as fully to Schedule III controlled substances as to those under Schedule II.

or administered in accordance with “a standard of medical practice generally recognized and accepted in the United States.” *Moore*, 423 U.S. at 139; *United States v. Smith*, 573 F.3d 639, 646-49 (8th Cir. 2009); *United States v. Armstrong*, 550 F.3d 382, 399 (5th Cir. 2008). Otherwise stated, “[A] licensed practitioner is not immune from the act solely due to his status, . . . but rather, because he is expected to prescribe or dispense drugs within the bounds of his professional practice of medicine.” *United States v. Collier*, 478 F.2d 268, 271-72 (5th Cir. 1973). From this principle flows the restriction that a non-registered supervisee may not administer controlled substances unless permitted to do so by the jurisdiction in which he or she practices. *See* Drug Enforcement Administration, Office of Diversion Control, Practitioner’s Manual: An Informational Outline of the Controlled Substances Act (2006) (available at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual_012508.pdf), at 28.

Missouri’s protocol fails these requirements. It involves a controlled substance administered for a medical purpose – and yet in a manner that is utterly foreign to accepted medical practice: a non-medical prison employee administers sodium thiopental through an IV-push. Quite unlike the act of a nurse handing off a pill, the IV-push of anesthesia is a highly specialized medical procedure in which the practitioner must rely on clinically-acquired “visual and tactile cues” to ensure that the drug is properly administered so that it actually sedates the patient. *See*

Plaintiffs' Opposition Ex. D (Affidavit of Dr. Heath), at 5-6; Plaintiffs' "Statement of Additional Material Undisputed Facts" ¶¶ 11-15 (ECF Doc. 226, at pp. 7-9).

The protocol is a stark deviation from the accepted practice of administering anesthesia, and Defendants present no evidence to the contrary. *Id.* We also know that Missouri law does not permit an IV-push to be performed even by Nurse M2, much less by non-medical prison employees.² And we know that the protocol departs from anesthesiologist M3's own medical practice, in which anesthesia is always administered by M3 himself or by the *anesthesia specialists* he is supervising. *See* Plaintiffs' Ex. 5 (also Def. Ex. 2) (M3 Depo.), at 81, 123.

Defendants, then, find no refuge in 21 C.F.R. § 1306.11(b), or in their attempt to launder the administration of a controlled substance through an "agent" whose very actions are anathema to the accepted practice of medicine. Finally, even if their novel argument were somehow sufficient for compliance with the CSA, it does not even mention the Food, Drug, and Cosmetic Act or its independent preemptive effect. Plaintiffs remain entitled to summary judgment.

²*See* Plaintiffs' Ex. 3 (also Defendants' Ex. 1) (M2 Depo.), at 162-63; 20 Mo. CSR § 2200-6.030(7)(G) ("Graduate practical nurses and licensed practical nurses shall NOT, under any condition . . . [a]dminister drug(s) via the intravenous push or intravenous bolus mode of delivery except when life-threatening circumstances require such administration."); Mo. Rev. Stat. §§ 334.104.2, 334.104.7, 334.402.1, 334.424.1; 20 Mo. CSR §§ 2150-9.040, 2200-4.200.3(G)(9) (providing only for administration by anesthesiologist, a nurse anesthetist, or a licensed anesthesiologist assistant, other than in dental or veterinary settings).

Respectfully submitted,

/s/ Joseph W. Luby

Joseph W. Luby, Mo. 48951
Public Interest Litigation Clinic
6155 Oak Street, Suite C
Kansas City, MO 64113
816-363-2795 • FAX 816-363-2799
Counsel for Plaintiff Winfield

David Barron, Ky. Bar 90269
100 Fair Oaks Lane, Suite 301
Frankfort, KY 40601
502-564-3948 • FAX 502-564-3949
*Counsel for Plaintiffs Ringo, Bucklew,
Middleton, and Winfield*

John William Simon, Mo. 34535
Constitutional Advocacy, L.L.C.
7413 Manchester Road, Suite 109
St. Louis, MO 63143
314-604-6982 • FAX 314-754-2605
*Counsel for Plaintiffs Bucklew,
Middleton, and Michael Taylor*

Cheryl Ann Pilate, Mo. 42266
Rebecca L. Kurz, Mo. 40451
Morgan Pilate LLC
142 North Cherry
Olathe, KS 66061
913-829-6336 • FAX 913-829-6446
*Counsel for Plaintiffs Bucklew, Middleton,
Ringo, and Smulls*

Jennifer Herndon, Mo. 37921
224 Hwy 67 North, # 122
Florissant, Mo 63031
314-831-5531 • FAX 314-831-5645
*Counsel for Plaintiffs Nunley,
Ferguson, Clay, Nicklasson,
and Franklin*

Michael J. Gorla, Mo. 26399
720 Olive Street, Ste. 1630
St. Louis, MO 63139
314-621-1617
Counsel for Plaintiff Ferguson

Christopher E. McGraugh, Mo 36301
Leritz, Plunkert & Bruning
555 Washington Avenue, Suite 600
St. Louis, MO 63101
314-231-9600 • FAX 314-231-9480
Counsel for Plaintiff Link

Elizabeth Unger Carlyle, Mo. 41930
P.O. Box 30418
Kansas City, MO 64112
816-525-6540 • FAX 866-764-1249
*Counsel for Plaintiffs Clay, Barnett,
Clayton, and Leon Taylor*

Eric W. Butts, Mo. 36184
720 Olive Street, Suite 1630
St. Louis, MO 63101
314-621-1617 • FAX 314-621-7448
*Counsel for Plaintiffs Christeson
and Rousan*

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was forwarded for transmission via Electronic Case Filing (ECF) this 18th day of July, 2011, to Andrew W. Hassell, Michael J. Spillane, and Stephen D. Hawke, Office of the Attorney General, P.O. Box 899, Jefferson City, Missouri 65101.

/s/ Joseph W. Luby
Joseph W. Luby

Counsel for Plaintiff John E. Winfield